



PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Qui, et al.

SERIAL NO.: 09/877,681

FILING DATE: June 8, 2001

TITLE: **CONTROLLED RELEASE
FORMULATION OF DIVALPROEX
SODIUM**

EXAMINER: not yet assigned

ART UNIT: 1615

DOCKET NO.: 6437.US.P4

I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C., 20231 on the date shown below.

Sarah Mayhew

Sarah Mayhew

Date

Assistant Commissioner for Patents
Washington, D.C. 20231

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Best
11-11-01

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- ☒ A copy of each cited reference is provided;
- ☐ Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard to payment of a fee:

- ☒ No fee is due because:
- ☒ This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
- ☐ Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
- ☐ This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of **\$180.00** is specified by 37 C.F.R. §1.17(p).

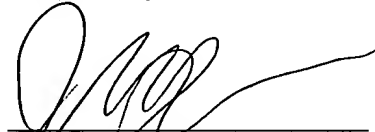
If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025. A duplicate sheet of this page is enclosed.

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Docket : 6437.US.P4

Respectfully submitted,


by J. Michael Dixon
Reg. No. 32,410

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|---------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------|---------------------------|
| FORM PTO-1449 (Rev. 2032) | U.S. Department of Commerce Patent and Trademark Office | Atty. Docket No.: 6437.US.P4 | Serial No.: 09/877,681 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | | Applicant Qui, et al. | Group: 1615 |
| | | Filing Date: 06/08/01 | |

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date (if appro.) |
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| | | | | | | |

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| EP 0 430 287 B2 | 06/05/91 | | | | |
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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| | | Abstract of Collins, et al., "Extended Release Formulations of Anticonvulsant Medications Clinical Pharmacokinetics and Therapeutic Advantages", CNS Drugs, New Zealand, 2000, 14/3 (203-212) |
| | | Abstract of Bialer, et al., "Criteria to Assess in Vivo Performance and Bioequivalence of Generic Controlled-Release Formulations of Carbamazepine", Epilepsia, United States, 1998, 39/5 (513-519) |
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| | | Abstract of Hussein, et al., "Pharmacokinetics of Valproate after Multiple-dose Oral and Intravenous Infusion Administration: Gastrointestinal-related Diurnal Variation", Journal of Clinical Pharmacology, United States, 1994, 34/7 (754-759) |
| | | Abstract of Wilder, et al., "Gastrointestinal Tolerance of Divalproex Sodium", Neurology, United States, 1983, 33/6 (808-811) |
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| EXAMINER | | DATE CONSIDERED: |

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.